K103487

OCT - 4 2011

Attachment A2

510 (k) Summary

1. Submitter Information

Company name	TaiDoc Technology Corporation
Contact person	Teling Hsu
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E-mail	*teling.hsu@taidoc.com.tw*
Date Prepared	November 22nd, 2010

2. Name of Device

Trade Names	FORA PNC100 Digital Pregnancy Test TD-5301 Pregnancy Test
Common Names	Pregnancy Test
Product Code	LCX
Classification Panel and Regulations	Human chorionic gonadotropin (hCG) test system Clinical Chemistry Class II 21 CFR 862.1155

3. Predicate Device

Trade/Proprietary Name:	One Step HCG Urine Pregnancy Test
Common/Usual Name:	Kit, Pregnancy Test, Over-the -Counter
Submitter	BLUE CROSS BIO-MEDICAL CO., LTD.
510 (k) Number	K071930

4. Device Description

The FORA PNC100 Digital Pregnancy Test and TD-5301 Pregnancy Test are *in vitro* diagnostic medical devices, which use the qualitative assay in determining human chorionic gonadotropin (hCG) concentration in urine. The assay is based on an two-site sandwich immunoassay technology.

TD-5301 Pregnancy Test consists of a test strip coated with reagents and enclosed in a plastic cassette. FORA PNC100 Digital Pregnancy Test consists of a meter and a plastic test stick containing a test strip. The meter has a slot where can be plugged with a test stick and activate the procedure. This device uses the same test strip, as TD-5301 Pregnancy Test.

5. Intended Use

For FORA PNC 100 Digital Pregnancy Test

The FORA PNC100 Digital Pregnancy Test is an *in vitro* diagnostic test device for the qualitative determination of human chorionic gonadotropin (hCG) in urine. It is intended for use as an aid in the early detection of pregnancy by lay users. Additional clinical examination should be performed to confirm the pregnancy.

The device uses visually read lateral flow technology for the detection of hCG and provides a digitally read result. The device is intended for home use.

For TD-5301 Pregnancy Test

The TD-5301 Pregnancy Test (Strip) is an *in vitro* diagnostic test device for the qualitative determination of human chorionic gonadotropin (hCG) in urine. It is intended for use as an aid in the early detection of pregnancy by lay users. Additional clinical examination should be performed to confirm the pregnancy.

The device uses visually read lateral flow technology for the detection of hCG. The device is intended for home use.

6. Comparison to Predicate Device

A method comparison was performed by two proposed devices and the predicate. Results show that there is over 99% agreement compared with the predicate. The

visual reading of lines of TD-5301 by lay users yields the same results as the digital readout obtained by FORA PNC100. The FORA PNC100 Digital Pregnancy Test and TD-5301 Pregnancy Test are substantially equivalent to the One Step HCG Urine Pregnancy Test (K071930).

7. Performance Studies

Test strip used with FORA PNC100 Digital Pregnancy Test and TD-5301 Pregnancy Test is identical. The sensitivity, specificity and interference, in-use and storage stability studies were tested and verified with both the proposed devices.

Software validation and meter reliability was performed specifically to ensure the performance of FORA PNC100 electronic read-out result. The meter of FORA PNC100 Digital Pregnancy Test meets the safety and EMC requirements of IEC/EN 61010-1:2001, IEC/EN 61010-2-101:2002, EN 61326: 2006, IEC 61000-4-2.

A user study was conducted to evaluate two application methods and the easiness of use by following the instructions, and the results demonstrated that the instruction manual of FORA PNC100 Digital Pregnancy Test and TD-5301 Pregnancy Test is understandable and clear enough for user, and devices are easy to operate by following the instructions.

8. Conclusion

The FORA PNC100 Digital Pregnancy Test and TD-5301 Pregnancy Test demonstrate satisfactory performance and are suitable for its intended use. The FORA PNC100 Digital Pregnancy Test and TD-5301 Pregnancy Test are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 04 2011

TaiDoc Technology Corporation
c/o Teling Hsu
Manager, Regulatory Affairs
3F, 5F, No. 127, Wugong 2nd Rd.
Wugu Township, Taipei County
24888 Taiwan

Re: K103487
Trade Name: Fora PNC100 Digital Pregnancy Test; TD-5301 Pregnancy Test Strip
Regulation Number: 21 CFR 862.1345
Regulation Name: Human chorionic gonadotropin test system
Regulatory Class: II
Product Codes: LCX
Dated: September 22, 2011
Received: September 27, 2011

Dear Teling Hsu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Attachment A1

Indications for Use

510(k) Number: k103487

Device Name: FORA PNC100 Digital Pregnancy Test

Indications for Use:

The FORA PNC100 Digital Pregnancy Test is an *in vitro* diagnostic test device for the qualitative determination of human chorionic gonadotropin (hCG) in urine. It is intended for use as an aid in the early detection of pregnancy by lay users. Additional clinical examination should be performed to confirm the pregnancy.

This device uses visually read lateral flow technology for the detection of hCG and provides a digitally read result. The device is intended for home use.

Prescription Use _____	AND/OR	Over the Counter Use ___X___
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) 103487

Indications for Use

510(k) Number: k103487

Device Name: TD-5301 Pregnancy Test

Indications for Use:

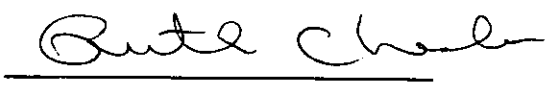
The TD-5301 Pregnancy Test (Strip) is an *in vitro* diagnostic test device for the qualitative determination of human chorionic gonadotropin (hCG) in urine. It is intended for use as an aid in the early detection of pregnancy by lay users. Additional clinical examination should be performed to confirm the pregnancy.

This device uses visually read lateral flow technology for the detection of hCG. The device is intended for home use.

Prescription Use _____ AND/OR Over the Counter Use ___X___
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



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